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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/435,576	CHEN ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,18,19,21,22,25-29,31-54,57-71 and 76-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13, 18-19, 21-22, 25-29, 31-54, 57-71, and 76-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Request for Continued Examination, Terminal Disclaimer, and Remarks filed 9/8/06 is acknowledged. Claims **1-13, 18-19, 21-22, 25-29, 31-54, 57-71, and 76-81** are pending in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13, 18-19, 21-22, 25-29, 31-54, 57-71 and 76-81 are rejected under 35 U.S.C. 102(b) as being anticipated by Alberts et al (5,376,383).

Alberts discloses a method of lowering plasma cholesterol levels by administering to a subject a time-controlled drug-delivery device containing a water-soluble HMG-CoA reductase inhibitor (lovastatin, pravastatin, etc). Alberts discloses that using a sustained or controlled release provides for a single dose to yield an equivalent or improved effect as that of a rapid release formulation (col. 1, lines 39-50 and abstract). Additionally, the formulation lowers the amount of peak drug plasma concentration in the blood; thus the potential side effects of the drug are reduced. The controlled release is over a 6 to 24 hour period (col. 2, line 63). Alberts discloses that this controlled release can be achieved by a variety of procedures known to those skilled in the art and discloses various controlled released matrices in the examples. The procedures suitable for the invention are diffusion-controlled systems, osmotic devices, dissolution controlled matrices, and erodible/degradable matrices (col. 3, lines 1-2). Lastly it

should be noted that lovastatin hydrolyzes in vivo to form its acid form, lovastatin acid. The examples provide a controlled device comprising a core and coat, which is substantially similar to instant disclosure Table 1's general formula.

* Note that although the prior art does not explicitly state the instant functional limitations, it is the examiner's position that the instant functional limitation is inherent since Albert's discloses a controlled release rate over an 18-hour period wherein the tablets is substantially similar to Table 1. Thus, the Tmax would inherently fall within instant range. The recitation of a newly discovered function inherently possessed by the prior art, does not make distinguish it form the prior art. Further, it is the applicant's burden to prove otherwise. See In re Best, 195 USPQ 430 (CCPA 1977).

Response to Arguments

Applicant argues that Alberts does not inherently provide the instant Tmax and inherency requires that the Tmax must be necessarily present. Applicant argues that Lescol is a once a day controlled release dosage form of fluvastatin and has a Tmax of 2.5 to 3 hours and thus not all controlled release dosage form comprising hydroxyl substituted naphthalene will inherently have the instant Tmax.

Applicant's arguments filed 9/8/06 have been fully considered but they are not persuasive. The examiner recognizes that inherency requires that an element must be necessarily be present, however as noted in *In re Best*, 195 USPQ 430 (CCPA 1977) the Patent Office can require the applicant to prove that a subject matter shown in the prior art does not possess a characteristic when there is reason to believe that the functional limitation asserted to be critical in establishing novelty in the claimed subject matter is possessed by the prior art. The burden is

initially on the examiner to provide a rationale for inherency, which then shifts to the applicant to rebut the examiner's position with evidence since the United States Patent Office does not have the capabilities or the facilities to test products for inherent features. See MPEP 2112. In instant case, the examiner refers to Table 1 in the instant disclosure to provide the rationale. Applicant discloses that the general structure in Table 1 provides the instant functional limitations. A careful look at Table I demonstrates that the instant invention only requires a core and an outer coating. The seal coat, an inner coat, and overcoat are not required since the claimed range encompasses zero. Zero clearly implies that the coating is not required. Therefore, examiner points out that the instant structure as defined in Table 1 and that of the prior art are substantially the same used for the same purpose. See the examples in Alberts. According to the MPEP, "A rejection under 35 U.S.C. 102/103 can be made when the prior art product **seems** to be identical except that the prior art is silent as to an inherent characteristic."

It should be noted for the record that examiner has not suggested that applicant experiment on humans to establish patentability. The examiner has merely stated that it is applicant's burden to provide evidence that the instant functional limitation is not inherent.

Applicant argues that McClelland teaches a similar device as taught by Albert and the Tmax is less than 5.

The examiner acknowledges that McClelland's device is similar to the device disclosed in Example 3 of US '383. However, the examiner points out that example 3 has a release of less than 14 hours and the examiner's rationale is based on example 10, which has a release over an 18-hour period and the same core as disclosed in the instant specification.

Applicant argues that Lescol is a once a day controlled release dosage form of fluvastatin and has a Tmax of 2.5 to 3 hours and thus not all controlled release dosage form comprising hydroxyl substituted naphthalene will inherently have the instant Tmax.

The relevance of this argument is unclear since Lescol is not the product taught in US 379; thus this is not a comparison of the closest prior art. The examiner points out that the examiner has made a sound rationale that the Tmax is necessarily taught in US '379. This rationale is not based on the "rash" assumption that the prior art teaches the instant drug in a controlled release device and thus must necessarily teach the Tmax. Again, the examiner has pointed out that the prior art's device is substantially identical to the instant invention and the only teaching lacking is the exemplification of lovastatin.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-13,18, 19, 21, 22, 25-29, 31-54, 57-71 and 76-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,837,379 to Chen et al by itself or in view of Cheng et al (Evaluation of Sustained/Controlled Release dosage forms of 3-Hydroxy-3-Methylglutaryl-Coenzyme A(HMG-CoA) Reductase Inhibitors in Dogs and Humans, Pharmaceutical Research (1993), 10:1683-1687).

Chen et al disclose a once daily pharmaceutical tablet having a 1) compressed core contains a medicament, a water-soluble osmotic compound, and one or more osmotic polymers, and 2) a membrane coating containing a water insoluble pharmaceutically acceptable polymer and an enteric polymer. See abstract. Although nifedipine is exemplified, Chen teaches various water-insoluble medicaments that may be utilized, including instant lovastatin. See column 2, line 64. The composition may additionally have dispersants, lubricants, dyes, and other additives that are conventionally utilized in the art. See column 5, lines 63-65. More specifically, Chen et al teach the medicament granules contain nifedipine, povidone (osmotic polymer), lactose (osmotic agent), and sodium lauryl sulfate (surfactant). The granules are compressed with lactose, Polyox WSR, and Myvaplex and coated with a color coating contains dye, sodium chloride, and water. The color coating is coated with a sustained release coating; followed by an enteric coating containing HPMC phthalate, pore forming agent, talc, and plasticizer. See examples. Lastly it should be noted that lovastatin hydrolyzes in vivo to form its acid form, lovastatin acid.

Chen does not exemplify lovastatin in the controlled release device nor specify the instant functional limitations.

Cheng et al teach controlled release device containing lovastatin and a sustained release matrix for the treatment of hypercholesterolemia. Cheng discloses that lovastatin hydrolyzes in vivo to form its corresponding beta-hydroxyacid, which are potent inhibitors of HMG-CoA reductase. See page 1683. Further, Cheng discloses that the liver, the target organ, more efficiently extracts lovastatin and simvastatin than their corresponding beta-hydroxyacid. Thus, the use of controlled release device allows for an equal or better therapeutic value. Table II teaches the total HMG-CoA reductase inhibitors (lovastatin and its acid form) pharmacokinetic parameters (AUC, the Cmax, Tmax, AUC ratio of 0.94, 1.03, 0.43, and 0.52, and Cmax ratio of 0.66, 0.64, 0.16, and 0.13) in dogs receiving various lovastatin dosage forms. See page 1685. Table V teaches the pharmacokinetics of simvastatin administered to humans. See page 1687.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Chen et al and include the instant lovastatin in the controlled release dosage form. One would have been motivated to do so since Chen teaches a variety of medicaments that would benefit from the use of the instant controlled release formulation and teaches the instant active as one of the suitable medicaments. Therefore, one could reasonably expect similar results by including lovastatin in Chen's controlled release device.

With regard to the instantly claimed Tmax and functional limitations, it is the examiner's position that Chen's controlled release device would meet the instant functional limitations since Chen's controlled release device is substantially similar in structure and formulation to applicant's dosage form described in the specification; in particular note Table I of instant specification wherein applicant's teaches the general formula of Table I provides the functional limitation. It is noted that the applicant does not claim the controlled release structure in the

claims and thus the examiner is permitted to look to the instant specification to define the controlled release device in terms of structure that provides the instantly claimed functional limitations. Therefore, it is the examiner's position that both would function similarly if not the same since the structures of the instant invention and that of the prior art are the same.

Secondly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further look at Cheng et al and specifically utilize lovastatin in Chen's controlled release device. One would have been motivated to do so since Cheng teaches lovastatin is an effective drug in reducing cholesterol serum levels in humans and it is beneficial to utilize a controlled or sustained release device. Therefore, Cheng provide a further motivation to specifically utilize lovastatin as the drug of choice if one desired to treat cholesterol serum levels. Further, although Cheng utilizes an animal model for drawing the conclusions that controlled release devices provide a better efficacy of lovastatin, it is conventional in the pharmaceutical research to draw conclusions from animal models and apply them to humans.

Response to Arguments

Applicant argues that Chen et al is directed to a controlled release dosage form but teaches various drugs including the instant lovastatin, fluvastatin, simvastatin, or pravastatin. However, applicant argues that the only in-vivo data provided is not related to the instant HMG-CoA Reductase Inhibitors. Applicant argues that none of the examples or information is provided for the instant HMG-CoA Reductase Inhibitors.

Applicant's arguments filed 9/8/06 have been fully considered but they are not persuasive. Firstly, the examiner recognizes that HMG-CoA Reductase Inhibitors are suggested and not exemplified. Hence, the examiner makes the rejection under obviousness and as

applicant is well aware, in an obviousness rejection, the prior art need only suggest the instant invention. In instant case, Chen is generally directed to a controlled release device for a once-a-day administration for water-insoluble drugs including the instant HMG-CoA Reductase Inhibitors, to increase patient compliance. See column 2, lines 64-65. Although the pharmokinectics of nifendipine are exemplified, a skilled artisan one would have been motivated to substitute nifendipine with the instant lovastatin and expect similar pharmacokinetic values since Chen clearly suggests the use of other drugs in place of nifedipine. It should be noted that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). The examiner points out that Chen need not exemplify every single drug taught to be suitable in order to render the instant invention obvious.

Applicant argues that the size of the genus is not sufficiently small as to render the each member inherently disclosed. Applicant argues that Chen does not provide any motivation to select lovastatin. Applicant argues that nifedipine and lovastatin are not structurally similar. Applicant argues that the pharmacokinetics of drugs are different and Chen does not provide any guidance in preparing a dosage form with the instant hydroxyl substitute naphthalene. Applicant argues "assuming one skilled in the art could formulate an alkyl ester of hydroxy substituted naphthalene in accordance with the teachings of Chen et al. to achieve the claimed Tmax parameters, such formulation would be a result of optimization of conditions."

Firstly, the examiner points out that applicant's arguments with regard to genus-species is not relevant to the instant rejection since the rejection has not made an anticipation rejection and rather made under obviousness. Thus a skilled artisan need not "immediately envisage" the use

of lovastatin in the dosage form since this is a requisite for anticipation and not obviousness. The examiner has not purported that a skilled artisan would immediately envisage the use of lovastatin, rather the examiner's position is that it is obvious to use lovastatin since Chen teaches lovastatin as a suitable drug to use in the controlled release dosage form. Thus, the motivation to use lovastatin comes from US '379 itself. Therefore, the motivation of utilizing lovastatin is within the disclosure of Chen itself. The examiner points out that the selection of a drug is prima facie obviousness depending on the disease to be treated. Thus, a skilled artisan would have been motivated to select lovastatin from the drugs suggested by Chen et al, to treat cholesterol levels. Moreover, a skilled artisan would ***reasonably*** expect that the Chen's controlled release dosage form would function the same irrespective of the drug utilized since Chen's general discloses is to a controlled release device that provides controlled release of a medicament in order to maintain therapeutic serum levels of the medicament.

Secondly, the examiner has not purported there is a structural similarity with nifedipine and lovastatin. The examiner notes the difference in pharmacological effects and the structure of the compounds. The examiner's position is that Chen's controlled release device is similar, if not same, to the instantly claimed controlled device and thus the prior art's controlled release device will meet the instantly claimed functional limitations including the instant Tmax. The premise is not that one would expect similar results since nifedipine and the instant alkyl esters of hydroxyl substituted naphthalenes are the same.

Thirdly, the examiner recognizes that each drug has its own physical characteristics and this must be given consideration when formulating the dosage form. Again it is pointed out that Chen generally teaches a controlled release device that provides controlled release of a water-

insoluble medicaments, *in general,* with the purpose of maintaining the serum levels. Thus, the inventive thrust of US '379 is the device and not the specific drug. The criticality of the drug as taught by Chen is that it is water-insoluble. Therefore, there is ***reasonable*** expectation of similar results in substituting nifedipine with lovastatin since both are water-insoluble drugs, as taught by Chen. It is further pointed out that the instant rejection is made under obviousness and optimization is not inventive in view of the guidance provided by the prior art. As clearly acknowledged by applicant, when formulating the dosage form comprising hydroxy substituted naphthalene, one would optimize the conditions to obtain the dosage form. The examiner points optimization via routine experimentation is not indicative of unexpectedness.

Applicant argues there is not statement of the Tmax and there is not suggestion that the in-vivo plasma levels achieved in the example of Chen would be desired for the instant drug class.

With regard to Chen's lack of the teaching of a Tmax or recognition of the criticality of the Tmax, it is pointed out that there is no requirement that a skilled artisan in the art has to recognize inherent properties at the time of invention, the only requirement is that that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

As set forth in the rejection above, it is the examiner's position that Chen's controlled device would necessarily provide the instant Tmax. The examiner points out that United States Patent Office does not have the facilities to test products for the properties they may or may not impart, i.e. the pharmacological properties provided by Chen's controlled release dosage form. Thus, the examiner must make a sound rationale as to why the prior art's dosage form is capable

of meeting the instantly claimed functional limitations including the instantly claimed Tmax. The rationale is as follows: The examiner points out that Chen teaches a core containing the drug, povidone (a water-swellable polymer), an osmotic agent (lactose), and sodium lauryl sulfate (surfactant) in applicant's amount disclosed in Table I. The core is coated with a color coating containing a dye and sodium chloride (osmotic agent). The prior art's color coat is comparable to applicant's seal coat. Then a sustained release coating containing Eudragit S (enteric polymer), and a plasticizer in applicant amount disclosed in Table I. The prior art's sustained release coat is comparable to applicant's inner coat. Lastly, the tablet is again coated with an enteric coating polymer containing an enteric polymer, a pore-forming agent (channeling agent), acetyltributyl citrate (plasticizer). The prior art's enteric coat is comparable to applicant's overcoat. Therefore, it can be seen that this device is the same as the described in instant specification of the preferred controlled release device that provides functional limitations of the instant application. Thus, it is the examiner's position that Chen's controlled release device would function similarly. It is pointed out that the examiner has provided a rationale that the prior art would function the same; thus the burden has shifted to applicant to prove otherwise. As noted in *In re Best*, the Patent Office can require the applicant to prove that a subject matter shown in the prior art does not possess a characteristic when there is reason to believe that the functional limitation asserted to be critical in establishing novelty in the claimed subject matter, is possessed by the prior art. As required the examiner has provided a rationale for inherency and thus the burden has shifted to the applicant. The examiner suggests the applicant compare Chen's device with the instant invention to substantiate applicant's arguments.

Applicant argues that Lescol is a once a day controlled release dosage form of fluvastatin and has a Tmax of 2.5 to 3 hours and thus not all controlled release dosage form comprising hydroxyl substituted naphthalene will inherently have the instant Tmax.

The relevance of this argument is unclear since Lescol is not the product taught in US 379; thus this is not a comparison of the closest prior art. The examiner points out that the examiner has made a sound rationale that the Tmax is necessarily taught in US '379. This rationale is not based on the "rash" assumption that the prior art teaches the instant drug in a controlled release device and thus must necessarily teach the Tmax. Again, the examiner has pointed out that the prior art's device is substantially identical to the instant invention and the only teaching lacking is the exemplification of lovastatin.

For the reasons above, the rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13, 18, 19, 21, 22, 25-47, 76-77, and 80 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

claims of copending Application No. 10/603254 is withdrawn in view of the Terminal Disclaimer filed 5/26/06.

Claims 1-13, 18, 19, 21, 22, 25-47, 76-77, and 80 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,485,748 in view of Remington's Pharmaceutical Science (18th edition, 1990). Although the conflicting claims are not identical, they are not patentably distinct from each other because since they encompass similar subject matter.

Instant application is directed to a controlled release oral solid dosage form for the reduction of serum cholesterol levels containing lovastatin and a controlled release carrier wherein the said dosage form has certain functional limitations upon consumption of the said dosage form.

US '748 is directed to a controlled release oral solid dosage form containing a compressed core with a slightly soluble to practically insoluble in water medicament and a membrane coating. The specification defines lovastatin as a drug that as a soluble.

Lovastatin is defined as a water-insoluble drug and sparingly soluble in alcohol in Remington's Pharmaceutical Sciences. See page 857-858.

Although US patent does not claim the functional limitation as seen in instant application, the controlled dosage form of US patent '595 would function in a similar manner as instantly claimed dosage form since both claim the same drug and the same controlled release structure. Although US patent '748 recites a generic slightly water-soluble drug to practically insoluble drug, the specification defines lovastatin as a drug that falls within this category. Further,

Remington's Pharmaceutical Sciences defines lovastatin as a water-insoluble drug. Thus, the instant application and US patents are related genus-species, wherein instant application recites the species and the species falls within the generic scope of the US patent '748 wherein the specification defines lovastatin as a water-insoluble drug.

Response to Arguments

Applicant argues that US ' '748 do not claim or teach a controlled dosage form that with the instant Tmax.

Applicant's arguments filed 9/8/06 have been fully considered but they are not persuasive. With regard to US '748, '748 also claims the same structure and claims the medicament is a slightly to practically insoluble in water at 25 degrees Celsius. The specification defines lovastatin as a drug that falls into this definition. Thus, the claims of instant application and US '748 have overlapping subject matter. Again claiming a functional limitation of a product does not change the product itself; thus the instant product and US patent are obvious over each other.

Conclusion

All the claims remain rejected at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharmila S. Gollamudi
Examiner
Art Unit 1616